

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2005N-0343]

*DUR*  
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Certifier J. Coote

**Agency Emergency Processing Under Office of Management and Budget  
Review; Guidance for Requesting an Extension to Use Existing Label Stock  
After the Trans Fat Labeling Effective Date of January 1, 2006**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). FDA is preparing a guidance document to notify the public of procedures being implemented by the agency to assist firms that wish to request, on a case-by-case basis upon an appropriate showing, an extension to use existing label stock after the effective date of the *trans* fat labeling final rule. This notice solicits comments on the proposed collection of information associated with the guidance document entitled "Guidance for Requesting an Extension to Use Existing Label Stock After the *Trans* Fat Labeling Effective Date of January 1, 2006."

**DATES:** Fax written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*. FDA is requesting approval of this emergency processing by *[insert date 7 days after date of publication in the Federal Register]*.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

**SUPPLEMENTARY INFORMATION:** FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j)) and 5 CFR 1320.13. FDA issued a final rule (the *trans* fat final rule) on July 11, 2003 (68 FR 41434) to require food labels to bear the gram amount of trans fat without a percent Daily Value (% DV) directly under the saturated fat line on the Nutrition Facts panel (<http://www.cfsan.fda.gov/~acrobat/fr03711a.pdf>). The *trans* fat final rule amended paragraph (c)(2) of § 101.9 *Nutrition Labeling of Food* (21 CFR 101.9). The effective date for the *trans* fat final rule is January 1, 2006. However, FDA has been advised by some businesses that they may experience hardship in revising their labels in time to meet the compliance date for *trans* fat labeling. Therefore, the agency believes that it would be appropriate to consider, on a case-by-case basis upon an appropriate showing, whether to exercise enforcement discretion with respect to the January 1, 2006, effective date for *trans* fat labeling for some businesses, so that these businesses would have the option of using some or all of their existing label stock that does not comply with the *trans* fat final rule.

FDA intends to notify the public, in a level 1 guidance document issued under the good guidance practices regulation (21 CFR 10.115), of the factors it intends to consider in granting or denying such requests and the process businesses may use to request the agency's consideration for enforcement discretion on *trans* fat labeling requirements. At a later date, FDA will announce the availability of a guidance entitled "Guidance for Requesting an Extension to Use Existing Label Stock After the *Trans* Fat Labeling Effective Date of January 1, 2006." The guidance will provide voluntary recommendations on the process for firms that wish to request an extension to use existing label stock after the effective date of the *trans* fat final rule.

Because this guidance involves a collection of information, the PRA is implicated. However, the delay associated with normal PRA clearance procedures can reasonably be anticipated to prevent or disrupt the collection of information during a time period within which businesses would be most likely to make the request for the use of existing label stock before the effective date of January 1, 2006. As a result, given the need for immediate action, FDA requests emergency processing of this collection of information request.

With respect to the following proposed collection of information, FDA invites comments on the following topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on

respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

*Title:* Guidance for Requesting an Extension to Use Existing Label Stock After the *Trans* Fat Labeling Effective Date of January 1, 2006.

*Description:* This policy provides guidance to FDA and the food industry about when and how businesses may request that the agency consider enforcement discretion for the use of some or all existing label stock, that does not declare *trans* fat labeling in compliance with the *trans* fat final rule, on products introduced into interstate commerce on or after the January 1, 2006, effective date.

#### **Industry Compliance With the *Trans* Fat Final Rule**

The *trans* fat final rule affects almost all manufacturers of packaged, labeled food sold in the United States. FDA believes that most businesses, including small businesses, should not have difficulty meeting the January 1, 2006, effective date of the *trans* fat final rule. However, under certain circumstances some businesses may want to request that the agency consider an extension of time to use current labels that are not in compliance with the *trans* fat final rule. Therefore, the agency believes that it would be appropriate to consider, on a case-by-case basis, whether to exercise enforcement discretion on the January 1, 2006, effective date for *trans* fat labeling for some businesses that can make an appropriate showing.

The agency intends to consider the following factors in any request from a firm for the agency's exercise of enforcement discretion:

- Whether products contain 0.5 gram or less *trans* fat;
- The explanation of why the request is being made;
- The number of existing labels that the firm is requesting to use;

- The dollar amount associated with the number of existing labels to be used; and
- The estimate of the amount of time needed, not exceeding 12 months, to exhaust the number of existing labels the firm is requesting to use.

Requests may be considered at any time before or after the January 1, 2006, effective date of the *trans* fat final rule. Firms may submit their requests in writing to FDA's Center for Food Safety and Applied Nutrition. Firms are encouraged to keep this letter of request for their records and should make a copy available for inspection to any officer or employee of the FDA who requests it. FDA intends to use the information in the letter to make decisions about whether a firm's product is subject to FDA's enforcement discretion for the *trans* fat labeling requirements.

FDA estimates the burden of the collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Written requests to FDA in year one	56	1	56	5	280
Written requests to FDA in year two	28	1	28	5	140
Onetime burden hours for years one and two					420

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

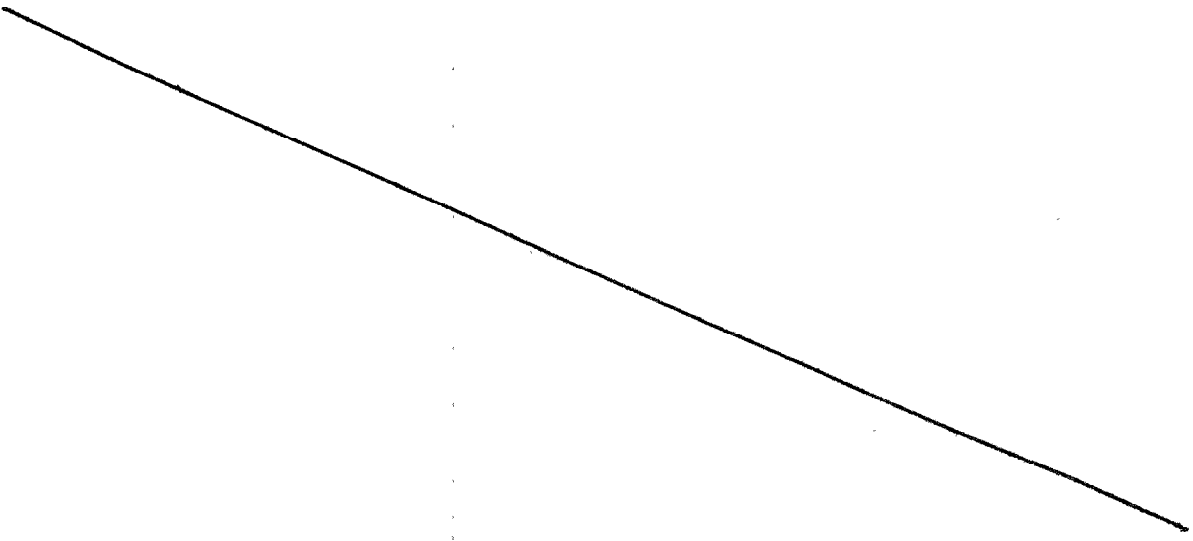
FDA estimates a 2-year time period during which these requests will be made following the issuance of this guidance. Beyond 2 years, FDA expects businesses to fully comply with the *trans* fat final rule, as it is unlikely that there will still be old labeling stock left to use.

FDA expects that, although all sizes of business are eligible, small businesses and very small businesses are the firms most likely to be able to demonstrate a need to request an extension to the *trans* fat labeling deadline. The agency has already received three requests from businesses regarding the *trans* fat labeling compliance date of January 1, 2006. Because small businesses

are more likely to submit requests for extensions, and most of the affected businesses are small, we use the number of small businesses as the base to calculate the reporting burden. The regulatory flexibility analysis of the *trans* fat final rule estimated that 11,180 small businesses will have to revise the label on their products as a result of the *trans* fat final rule. Given that only three businesses have submitted requests to FDA so far, FDA estimates that, in the first year following the issuance of the guidance, the total number of businesses that will request a labeling compliance extension from FDA can be estimated as approximately 0.5 percent of the number of small businesses, which equals 56.

FDA estimates that it will take one employee approximately 4 hours to put together a request to FDA and approximately 1 hour for a supervisor to look over the request before submitting it to the agency. Thus, each firm submitting a compliance extension request will need 5 hours of employee time to complete the request. Given that 56 businesses are expected to submit written requests in year one, the total burden hours for year one are 280.

In year two, FDA expects about one-half as many firms to request a labeling compliance extension. So for year two, 28 firms are expected to file a request for an extension to the labeling compliance date. Again, assuming



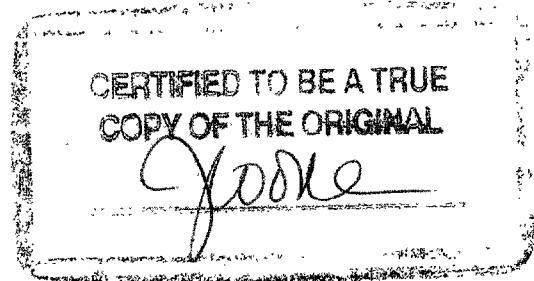
that it will take 5 hours to complete each request, the total burden hours for year two will be 140.

Dated: 8-26-05

August 26, 2005.

Jeffrey Shuren

Jeffrey Shuren,  
Assistant Commissioner for Policy.



[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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